MAY 3 1 2012

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: k111382.

1. **Submitter's Identification:**

Cellulose Concepts LLC
2867 Industrial Plaza Drive, Suite C
Tallahassee, FL 32301

Phone: 850 391 9859

Date Summary Prepared: December 6, 2011

2. **Name of the Device:**

Proprietary name: CELVER®

3. **Classification:** Unclassified

Product Code: FRO

4. **Common or Usual Name:**

Common Name: Absorbent Antimicrobial Wound Dressing

5. **Predicate Device Information:**

K013814 ConvaTec Absorbent Antimicrobial Wound Dressing

6. **Description:**

CELVER® is a sterile silver moist wound dressing. CELVER® is composed of sodium carboxymethylcellulose, sodium lactate and ionic silver imbedded into a non-woven 100% cotton substrate.

In contact with wound exudate, the highly adsorbent dressing creates a soft cohesive gel that forms an intimate contact with the wound surface and maintains a moist wound-healing environment.

The construction of the bandage provides for easy removal with minimal

residue left on the wound.

The bandage dimensions are 4" x 4" and is further perforated into 15 equal sections appropriately ¾" x 1 ½" for flexibility and ease of use.

7. Intended Use:

For prescription use, under the supervision of a health care professional, CELVER® may be used for the management of partial thickness (second degree) burns, diabetic foot ulcers, leg ulcers (venous stasis ulcers, arterial ulcer and leg ulcers of mixed aetiology) and pressure ulcers/sores (partial & full thickness).

8. Comparison to Predicate:

The predicate device and CELVER® are indicated for acute and chronic wounds. Both dressings are of a similar composition consisting of silver and absorbent padding to absorb wound exudate, and create a *moist* wound environment supportive of the healing process.

9. Performance Data:

Non-clinical: Verification, validation, and testing activities were conducted to establish the performance, functionality, and reliability characteristics of the CELVER® with respect to the predicate device.

Third party testing was performed including biocompatibility testing per ISO 10993-10:2002 and ISO10993-5:2009

The device passed all of the tests based on pre-determined Pass/Fail criteria.

10. Conclusions:

The data from the biocompatibility and non clinical tests show that the CELVER®is as safe and effective as the legally marketed predicate device.

Therefore we conclude that the CELVER®is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cellulose Concepts, LLC
% MDI Consultants, Incorporated
Ms. Maria F. Griffin
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

MAY 3 1 2012

Re: K111382
Trade/Device Name: CELVER
Regulation Class: Unclassified
Product Code: FRO
Dated: May 17, 2012
Received: May 21, 2012

Dear Ms. Griffin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): k111382

Device Name: CELVER®

Indications For Use:

For over-the-counter use, CELVER® may be used for minor abrasions, minor lacerations, minor cuts, minor scalds and 1st degree burns.

Prescription Use ____ **Over-The Counter Use__X___**

(Per 21 CFR 801 Subpart D) **OR** **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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Prescription Use X **Over-The Counter Use**_____

(Per 21 CFR 801 Subpart D) **OR** **(21 CFR 807 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

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